K000463

JUN - 1 2000

510(k) Summary

Safety and Effectiveness

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: **Address:**	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Telephone Number: **Facsimile Number:**	(310) 645-8200 (310) 645-9999
Contact Person:	Edward M. Levine, Ph.D. Director of Clinical Affairs
Date of Preparation:	April 4, 2000
Device Name: **Trade:**	IMMULITE® H. pylori IgG and IMMULITE® 2000 H. pylori IgG
Catalog Number:	LKHEQ1 (100 tests), LKHEQ5 (500 tests) and L2KHQ2 (200 tests), L2KHQ6 (600 tests)
Common:	Reagent system for the detection of H. pylori IgG antibodies to Helicobacter pylori in human serum.
Classification:	Class I device, 83-LYR (21CFR 866.3110)
Manufacturer:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, CA 90045 (The Quality System of Diagnostic Products Corporation is registered to ISO 9001:1994)
Establishment Registration Number	DPC's Registration Number 2017183
Substantially Equivalent Predicate Device:	Sigma Diagnostics Helicobacter pylori HM-CAP™ (K944159)
Description of Devices:	IMMULITE H. pylori IgG and IMMULITE 2000 H. pylori IgG are clinical devices for use with their respective IMMULITE and IMMULITE 2000 Automated Immunoassay Analyzers.

Intended Use of the Device:

For in vitro diagnostic use with the IMMULITE (or IMMULITE 2000) Analyzer – for the qualitative detection of IgG antibodies to Helicobacter pylori in human serum from symptomatic adults as an aid in the diagnosis of Helicobacter pylori infection.

Performance Equivalence:

Diagnostic Products Corporation (DPC) asserts that IMMULITE H. pylori IgG and IMMULITE 2000 H. pylori IgG produce substantially equivalent results to other commercially marketed H. pylori IgG assays, such as Sigma Diagnostics H. pylori HM-CAP, as well as, endoscopic biopsy evaluations. The IMMULITE and IMMULITE 2000 H. pylori IgG assays and Sigma Diagnostics H. pylori HP-CAP are intended strictly for *in vitro* use to aid in the determination of serological status to Helicobacter pylori

Technology Comparison:

Provided for the reviewer is a comparison of DPC's IMMULITE and IMMULITE 2000 H. pylori IgG technology vs. the Sigma Diagnostics Helicobacter pylori HM-CAP EIA technology. This section does not contain any new information for a reviewer who is familiar with DPC's IMMULITE or IMMULITE 2000 analyzers based upon the review of previously cleared and commercially marketed IMMULITE or IMMULITE 2000 products.

IMMULITE H. pylori IgG is a solid-phase, two-step chemiluminescent enzyme immunoassay. The solid phase, a polystyrene bead enclosed within an IMMULITE Test Unit, is coated with partially purified Helicobacter pylori antigen.

Prediluted patient sample (1-in-21 dilution) and a protein-based buffer are simultaneously introduced into the Test Unit, and incubated for approximately 30 minutes at 37°C with intermittent agitation. During this time, H. pylori-specific IgG in the sample binds to the H. pylori antigen-coated bead. Unbound serum is then removed by a centrifugal wash.

An alkaline phosphatase-labeled anti-human IgG antibody is introduced, and the Test Unit is incubated for approximately another 30-minute cycle. The unbound enzyme conjugate is removed by a centrifugal wash. Substrate is then added, and the Test Unit is incubated for a further 10 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple readings. The bound complex -- and thus also the photon output, as measured by the luminometer -- is related to the presence of H. pylori IgG in the sample. A result is then obtained by comparing the patient result to a stored Master Curve.

IMMULITE 2000 H. pylori IgG is a solid-phase, two-step chemiluminescent enzyme immunoassay. The solid phase, a polystyrene bead added to an IMMULITE 2000 Reaction Tube, is coated with partially purified Helicobacter pylori antigen.

Prediluted patient sample (1-in-20 dilution) and a protein-based buffer are simultaneously introduced into the Reaction Tube, and incubated for approximately 30 minutes at 37°C with intermittent agitation. During this time, H. pylori-specific IgG in the sample binds to the H pylori antigen-coated bead. Unbound serum is then removed by a centrifugal wash.

An alkaline phosphatase-labeled anti-human IgG antibody is introduced, and the Reaction Tube is incubated for approximately another 30-minute cycle. The unbound enzyme conjugate is removed by a centrifugal wash. Substrate is then added, and the Reaction Tube is incubated for a further 5 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple readings. The bound complex -- and thus also the photon output, as measured by the luminometer -- is related to the presence of H. pylori IgG in the sample. A result is then obtained by comparing the patient result to a stored Master Curve.

The **Sigma Diagnostics Helicobacter pylori HM-CAP** kit utilizes the Enzyme Immunoassay (EIA) technique for the detection of antibody to H. pylori. Patient serum samples to be assayed for antibody are first diluted and incubated with the purified H. pylori antigen bound to the solid surface of the multi-well plate.

If the antibody is present in the patient's serum antigen-antibody complexes are formed. After washing the unbound serum from the well, peroxidase conjugated anti-human IgG is added to the well. During incubation the conjugate will bind to human antibody. After washing the unbound conjugate from the well, substrate is added and the system is incubated. The enzyme conjugate present will react with the tetramethylbenzidine (TBM) substrate, resulting in color development. The absorbance of the solution, measured at 450 nm, is directly related to the concentration of antibody to H. pylori.

Clinical Studies and Method Comparisons

IMMULITE H. pylori IgG was compared to clinical diagnosis by biopsy on 155 randomly selected retrospective specimens from patients suspected of H. pylori infection. A specimen was considered clinically positive if the culture test or both CLO and histology tests were positive. A specimen was considered clinically negative if none of the biopsy tests was positive.

		IMMULITE H. pylori			N	155
Clinical	Pos	64	3	2	Agreement	98.0%
Diagnosis	Neg	1	1	84		
		Pos	Ind.	Neg		

Sensitivity: 97.0% Central 95% Confidence Interval: 89.5% - 99.6%
Specificity: 98.8% Central 95% Confidence Interval: 93.6% - 100%

IMMULITE H. pylori IgG was also compared to a commercially available enzyme immunoassay for H. pylori IgG (Kit A) on 70 patient samples.

		IMMULITE H. pylori			N	70
	Pos	50	3	2	Agreement	91.4%
Kit A	Ind.	1	0	0		
	Neg	0	0	14		
		Pos	Ind.	Neg		

IMMULITE 2000 H. pylori IgG was compared to clinical diagnosis by biopsy on 155 randomly selected retrospective specimens from patients suspected of H. pylori infection. A specimen was considered clinically positive if the culture test or both CLO and histology tests were positive. A specimen was considered clinically negative if none of the biopsy tests was positive.

		IMMULITE 2000 H. pylori			N	155
Clinical	Pos	65	2	2	Agreement	98.7%
Diagnosis	Neg	0	2	84		
		Pos	Ind.	Neg		

Sensitivity: 97.0% Central 95% Confidence Interval: 89.6% - 99.6%
Specificity: 100.0% Central 95% Confidence Interval: 95.7% - 100%

IMMULITE 2000 H. pylori IgG procedure was also compared to the IMMULITE procedure on 197 samples with a concentration range from approximately 0.4 to 7.0 U/mL in a linear regression analysis, with the following results:

(IML 2000) = 0.96 (IML) + 0.05 U/mL r = 0.992

Means: 2.19 U/mL (IMMULITE 2000)
2.23 U/mL (IMMULITE)

Conclusion:

The data presented in this summary of safety and effectiveness is the data that the Food and Drug Administration used in granting DPC substantial equivalence for the IMMULITE H. pylori IgG and IMMULITE 2000 H. pylori IgG assays.

Edward M. Levine

Edward M. Levine, Ph.D.
Director of Clinical Affairs

5/17/00
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

JUN - 1 2000

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Edward M. Levine, Ph.D.
Director of Clinical Affairs
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045-5597

Re: K000463
Trade Name: IMMULITE® H. pylori IgG and IMMULITE® 2000 H. pylori IgG
Regulatory Class: I
Product Code: LYR
Dated: April 5, 2000
Received: April 10, 2000

Dear Dr. Levine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K000463

Device Name: **IMMULITE® H. pylori and IMMULITE® 2000 H. pylori**

Indications For Use:

IMMULITE® H. pylori and IMMULITE 2000 ® H. pylori are - For in vitro diagnostic use with the IMMULITE Analyzers – for the qualitative detection of IgG antibodies to Helicobacter pylori in human serum from symptomatic adults as an aid in the diagnosis of Helicobacter pylori infection.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000463

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)